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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,276	03/07/2001	John W. Erickson	207596	9981

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/720,276	ERICKSON ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/12/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47 and 49-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47 and 49-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claim 81 is added. Claims 1-46 and 48 were cancelled. Claims 47 and 49-81 are under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 47 and 49-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vazquez et al.[1]

In response to the rejection, Applicant argues that Vazquez et al. does not teach or suggest a method for inhibiting the development of drug resistance in an HIV infected mammal, as required by the preamble of the claims. Applicant also submits that Applicant has discovered a new property and a new method, neither of which is disclosed or suggested by the cited reference. Applicant also argues that Vazquez et al. has not provided a reasonable expectation of arriving at the claimed invention. Additionally, Applicant submitted a copy of an approval letter from US FDA for co-administration with ritonavir for the treatment of HIV infection in antiretroviral treatment experienced adult patients.

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[1] Vazquez et al. WO 95/06030, published March 02, 1995.

Applicant's arguments have been considered, however, it is not found persuasive. The claims are directed to a method comprising the active step(s) of administering a compound of the formula recited in the claims to HIV (retrovirus) infected mammal. In the instant case, Vazquez et al. teaches a composition encompassed by those recited in the claims. Vazquez et al. teaches that the compounds are effective as retroviral proteases inhibitors, in particular as inhibitors of HIV protease. [Abstract] Vazquez et al. also suggests the administration of the compounds to inhibit retroviral proteases. [Claims 15-20, page 273.] Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made to administer the compounds to an HIV infected mammal to inhibit retroviral proteases. Therefore, contrary to Applicant's arguments, Vazquez et al. did suggest the claimed method.

While it is noted that the preamble of the claims states that the claimed invention is a "method of inhibiting the development of a drug resistance", the cited recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Thus, while Applicant's arguments have been considered, it is not found persuasive.

Regarding, Applicant's submission that Applicant has discovered a new property and a new method, MPEP § 2112 provides, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. In the instant case, Applicant's discover of ability of the protease inhibitor to inhibit the development of drug resistance in a mammal does not further render this composition. Since this property is with the composition, the administration of the composition to an infected mammal would necessarily lead to the inhibition of the development of drug resistance in said mammal. In the instant it is unequivocal that Applicant's claims recite applying the same composition agent, in the same amount, to the same part of the body, as suggested by Vazquez et al. Because the same agent is applied to the same part of the body in the same amount, the result of that application must necessarily be the same as disclosed by Applicant. Otherwise Applicant's invention could not function as disclosed. Note specifically that it is clearly proper to refer to applicant's own disclosure to determine whether a prior art disclosure inherently meets a claimed limitation. See, e.g., *Ex parte Novitski*, 26 USPQ2d 1389 (BPAI 1993), wherein claimed process of administering ingredient to plant was held anticipated by prior art process of administering ingredient to plant, based on specification's disclosure that prior art ingredient inherently met claimed limitation. Because Applicant has not demonstrated any difference between the claimed processes and the process suggested by Vazquez et al., the rejection of record clearly must be maintained.

Additionally, contrary to Applicant's assertion Vazquez et al. has not provided a reasonable expectation of arriving at the claimed invention, Vazquez et al. clearly predicted the claimed method with a reasonable expectation of success. The claimed invention is directed to a method comprising the active step(s) of administering a compound of the formula recited in the claims to HIV (retrovirus) infected mammal. In the instant case, Vazquez et al. teaches an HIV protease inhibitor, wherein the inhibitor has the same formula as those recited in the claims. Vazquez et al. then suggested administration of the composition to inhibit HIV protease activity. Hence, there is nothing unexpected surrounding the administration of the HIV protease inhibitor to a mammal infected with HIV because the inhibitory activity of the inhibitor is well characterized by Vazquez et al.

Lastly, the submitted approval letter has been considered, while the Office congratulates Applicant on the approval, however, it should be noted that the claimed invention remains unpatentable over Vazquez et al. In the instant case, the claimed invention is indistinguishable from the method suggested by Vazquez et al., as discussed above.

As noted, the claims are directed to a method comprising the active step(s) of administering a compound of the formula recited in the claims to HIV (retrovirus) infected mammal.

Vazquez et al. teaches a compound having the same structure and empirical formula as those recited in the claims, when X is an O, R_5 is a C_4 alkyl, and Ar is an amino substituted phenyl. It is noted that the compound of Vazquez et al. is an isomer

of the compound recited in claims 51-59, 69-78 and 80; however, it should be noted that compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) See also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious). Hence, it is presumed that the isomer of Vazquez et al. has similar properties as those recited in the specified claims.

Vazquez et al. does not teach the administration of the compound to an HIV infected mammal.

However, Vazquez et al. teaches that the compounds are effective as retroviral proteases inhibitors, in particular as inhibitors of HIV protease. [Abstract] Vazquez et al. also suggests the administration of the compounds to inhibit retroviral proteases. [Claims 15-20, page 273.]

Hence, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer the composition to an HIV infected mammal. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to inhibit the action of HIV proteases. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because Vazquez et al. teaches that the compound inhibits HIV proteases.

In the instant case, it is noted that claims 60-62 require that the mammal be infected with a wild type HIV, mutant HIV having at least one protease mutation, and a mutant HIV having at least one reverse transcriptase mutation, respective. It is further noted that claims 64-67 and 78 are directed at requiring the mammal to be infected with a multidrug resistant mutant retrovirus, multidrug resistant HIV, a multidrug-resistant HIV-1, and a mutant retrovirus that is resistant to at least one antiviral agent selected from the group consisting of ritonavir, indinavir, amprenavir and saquinavir, respectively. Additionally, it is noted that claim 80 requires the mammal be infected with a multidrug-resistant HIV-1 comprising a protease with at least one mutation selected form the group consisting of V82F, I84V, G48V and V82A.

In summation, claims 60-62, 64-67, 78 and 80 require the mammal to be infected with variations of the HIV virus. To address these limitations, it should be noted that Vazquez et al. teaches a compound having the same formula as those recited in the claims. Vazquez et al. teaches that the compound inhibits retroviral protease, including HIV. In the instant case, Vazquez et al. explains that the correct processing of the precursor proteins by the retroviral protease is necessary for assembly of infectious virions. Vazquez et al. further provides an example. Vazquez et al. states that, as an example, "it has been shown that frameshift mutations in the protease region of the pol gene of HIV prevent processing of the gag precursor protein. It has also been shown through site-directed mutagenesis of an aspartic acid residue in the HIV protease active site that processing of the gag precursor protein is prevented." Hence, on the basis of this showing, Vazquez et al. suggests the administration of the compound having the

same formula as recited in the claims to inhibit retroviral replication by inhibiting the action of the retroviral proteases. [Paragraph bridging pages 1-2]

In view of this teaching, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer the compound to all HIV infected mammals, regardless of the condition of the virus. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to inhibit the action of HIV proteases. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because Vazquez et al. teaches that the compound inhibits HIV proteases.

4. Claims 47 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vazquez et al., as applied to claim 47, in view of Lisziewicz et al.[2]

Claim 81, which depends on claim 47, requires the method to further comprise the administration of at least one antiviral agent selected from the group consisting of ritonavir, indinavir, amprenavir and saquinavir--all protease inhibitors.

The significance of Vazquez et al., as applied to claim 47 is provided above.

In the instant case, Vazquez et al. does not teach or suggest the administration of least one antiviral agent selected from the group consisting of ritonavir, indinavir, amprenavir and saquinavir. However, Vazquez et al. suggested the administration of other antiviral agents with his protease inhibitor. [Lines 26-37, page 244, in particular.]

At the time the invention was made, Lisziewicz et al. teaches the following antiviral agents: ritonavir, indinavir, amprenavir and saquinavir. [Lines 29-38, column 5,

[2] Lisziewicz et al. U.S. Patent No. 6251874, filed 03/26/1998.

in particular.] Thus, at the time the invention was made, it would have been prima facie obvious to administer ritonavir, indinavir, amprenavir or saquinavir with the protease inhibitor of Vazquez et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to inhibit HIV protease activity. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because all are protease inhibitors.

Conclusion

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/